

K120701

510(k) Summary

FEB 7 2013

510(k) SUMMARY

ASPECT IMAGING's WRIST MRI SYSTEM

Applicant's Name:

Company name: Aspect Imaging Ltd.
Address: 27 Shaked St.
Industrial Area Hevel Modi'in
P.O. Box 926
Shoham, 60850
ISRAEL
Tel: +972-73-223-9000
Fax: +972-3-716-5606

Contact Person:

Official Correspondent: Ahava Stein
Company name: A. Stein – Regulatory Affairs Consulting
Address: Beit Hapaamon (Suite 213)
20 Hata'as Str. (Box 124)
Kfar Saba 44425
Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: September 19, 2012

Name of the device: M2 Wrist MRI System

Trade or proprietary name, if applicable: Magnetic Resonance Imaging System

Common or usual name: MRI System

Establishment Registration No.: TBD

Classification Name: Magnetic Resonance Imaging System

Classification: The subject of this 510(k) is the M2 Wrist MRI System, with the CFR classification sections 892.1000; Magnetic Resonance Imaging System with product code LNH.

Predicate Devices:

The M2 Wrist MRI System is substantially equivalent to the Orthone MRI System (manufactured by Oni Inc. and the subject of 510(k) K001773). A comparison table and detailed discussion are presented in Section 12 of this application.

Intended Use:

The **M2 Wrist MRI System** is intended for use as a magnetic resonance imaging device for producing transverse, sagittal and coronal images of the internal structure of the wrist (in patients with an arm length > 320mm). When interpreted by a trained physician, the resultant MR images provide information that can be useful in determining a diagnosis.

Technological Characteristics:

The Wrist MRI is a 1 Tesla high-performance solution, using NdFeB magnetic material, providing routinely 250 micron or better resolution. The system is Eddy – currents free with gradients which have high strength and a fast slew rate.

The Wrist MRI is designed to ensure maximum safety of operation. Its negligible external magnetic-field eliminates the need for a specially shielded room and other limiting operational procedures.

The Wrist MRI system's main components are:

- Magnet Sub-system
- Wrist Coil
- Electronics Cabinet
- Aspect Imaging Proprietary Software
- Computer
- Isolation Transformer

Technical Description of magnet subsystem:

- Field strength: 1.05 +/- 2% Tesla vertical Field, horizontal bore
- Bore opening size(H x W) 76 x 200 mm
- Magnet size: approx. 79 x 79 x 114 cm
- Magnet weight: approx. 930 kg
- Passive B0 shim system
- Field of View – 115 x 80 x 50 mm
- Resolution – Better than 250µm area pixel

Technical Description of gradient system:

- Type: Special purpose gradient system
- No Eddy current
- Gradient strength: 190 mT/m
- Slew rate: 400 T/m/sec

Comparison of Technological Characteristics with the predicate device:

The M2 Wrist MRI System has the same technological characteristics as the predicate device, i.e., the Orthone MRI System. Both devices contain the same basic components consisting of a magnet, a coil, a separate electronic cabinet or unit containing a control unit, a RF power amplifier, gradient amplifier, power distribution unit, and spectrometer. Furthermore, both devices contain a computer PC component and system software. Both the M2 MRI Wrist System and the Orthone MRI System are large devices with similar large dimensions and weight, although both of them are relatively compact MRI Systems as they are intended for small body parts as opposed to full body MRI systems.

The component specifications are comparable between the new MRI device and the predicate device. Both MRI devices use a 1 Tesla magnet as the basic scientific technology of the device. The basic device performance of the M2 Wrist MRI System and the Orthone MRI System are similar. There are some minor differences between the M2 Wrist MRI System and the Orthone MRI System, including slice thickness.

Though there are some minor differences in the characteristics of the two systems, these differences do not raise new questions of safety or efficacy. Furthermore, the M2 Wrist MRI System has passed all the required tests and standards for MRI devices, as did the Orthone MRI System. These tests include compliance with electrical and mechanical safety according to IEC 60601-1, electromagnetic compatibility according to IEC 60601-1-2 and specific testing for MRI devices according to the IEC 60601-2-33 and testing according to the applicable NEMA standards.

Non-Clinical Performance Data:

See Performance Standards

Performance Standards:

The following performance tests were performed on the M2 Wrist MRI System or its components:

- Electrical & Mechanical Safety (IEC 60601-1)
- Electromagnetic Compatibility (IEC 60601-1-2)
- Software Validation
- MR Image Quality Testing
- NEMA MS-1-2008 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS 3-2008 Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images (Image Uniformity Test)
- NEMA MS 4 (2006) Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices

- NEMA MS 5-2010 Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- NEMA MS 8 (2006) Characterization of the Specific Absorption Rate (SAR) for MRI Systems
- NEMA MS 10-2006 Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS 11-2006 Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging
- NEMA MS 12-2006 Quantification and Mapping of Geometric Distortion for Special Applications
- IEC 60601-2-33 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic (2007 (Second Edition) + A1:2005 + A2:2007)
- High Contrast Spatial Resolution Testing

In all instances, the M2 Wrist MRI System functioned as intended and/or met the requirements of the standard.

Clinical Performance Data:

Not Applicable

Conclusions Drawn from Non-Clinical and Clinical Tests:

The performance tests demonstrate that M2 Wrist MRI System may be safely and effectively used in acquiring wrist MR images. The software validation and performance tests demonstrate that the M2 Wrist MRI System meets its design and performance specifications and is substantially equivalent to the cleared Orthon MRI System.

Substantial Equivalence:

In summary, the indications for use of the M2 Wrist MRI System are substantially equivalent to the Orthon MRI system. Furthermore, the basic technological characteristics of the M2 Wrist MRI System are similar to the Orthon MRI System. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the M2 Wrist MRI System is substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2013

Aspect Imaging Ltd.
c/o Ms. Ahava Stein
Regulatory Consultant
20 HATA'AS ST (BOX 124)
KFAR SABA 44425
ISRAEL

Re: K120701

Trade/Device Name: M2 Wrist MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: January 20, 2013
Received: January 25, 2013

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K120701

Device Name: M2 Wrist MRI System

Indications for Use:

The **M2 Wrist MRI System** is indicated for use as a magnetic resonance imaging device for producing transverse, sagittal and coronal images of the internal structure of the wrist (in patients with an arm length > 320mm). When interpreted by a trained physician, the resultant MR images provide information that can be useful in determining a diagnosis.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120701